9/27/04

2855 JFW

NP EXPRESS MAIL LABEL NO.: EV 333487080 US

**PATENT** 

Attorney Docket No. 29191.707.201

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Jonathan C. HELLER et al.

Art Unit: 2855

Application No.: 10/645,863

Filed: August 20, 2003

Title: System of analyzing complex mixtures of biological and other fluids to identify biological state information

PATENT APPLICATION

Art Unit: 2855

Examiner: Not yet assigned

Of biological and other fluids to identify biological state information

PATENT APPLICATION

Art Unit: 2855

Examiner: Not yet assigned

Of biological and other fluids to identify biological state information

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

$\boxtimes$	This s	This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:							
		(1)	It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  OR						
		(2)	It is being filed within 3 months of entry of a national stage OR						
	$\boxtimes$	(3)	It is being filed before the mail date of the first Office Action on the merits OR						
		(4)	It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.						
	the fill nation a first	ing dat al stage Office	97(c). If this statement is being filed after the latest of: (1) three months beyond e of a national application; (2) three months beyond the date of entry of the as set forth in §1.491 in an international application; or (3) the mailing date of action on the merits, but before the mailing date of the earlier of a final office §1.113 or a notice of allowance under §1.311, then:						
		a certi	fication as specified in §1.97(e) is provided below; or						
		a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.							
	final c	37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:							
	A.	a certi	fication as specified in §1.97(e) is completed below; and						
	B.	-	tion under 37 C.F.R. §1.97(d) requesting consideration of this statement is tted herewith; and						
	C.		of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included he payment of other papers filed together with this statement.						
	-	Copies of each of the references listed on the attached Form PTO/SB/08 are enclosherewith.							
$\boxtimes$	-	Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPTHAT:							
		refere	ew of the voluminous nature of references, and the likelihood that these nces are available to the Examiner in the file history of the parent application l No. ), copies are not enclosed herewith.						
			If any of the foregoing publications are not available to the Examiner,  Applicant will endeavor to supply copies at the Examiner's request						

		accordance with 37 CFR 1.98 (a application publication listed on the because this U.S. patent application	iments and non-patent literature are enclosed in (2). (The U.S. patents and each U.S. patent the attached Form PTO-1449 are not enclosed was filed after June 30, 2003 or this international stage under 35 USC §371 after June 30, 2003 (see r 37 CFR 1.98 (a)(2)(i).
	There	are no listed references which are not	in the English language.
	The re	levance of those listed references whi	ch are not in the English language is as follows:
		ordance with MPEP 609 D in supp	m corresponding patent application(s), submitted port of the attached certification under 37 CFR
	Attach relevai	- · · · · · · · · · · · · · · · · · · ·	ending patent applications which may be deemed
	fees of		nereby authorized to charge the above-referenced es or credit any overpayment associated with this 2415 (Docket No.29191.707.201).
			Respectfully submitted,
			WILSON SONSINI GOODRICH & ROSATI
Dated:		9/23/04	By: U.P. Peter Eng, Reg. No. 39,666
Palo A (650) 4	493 <b>-</b> 930	94304-1050	
Custon	HOL INU.	V217/1	

PTO/SB/08A (08-03)

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	P.C.	.0	*	Complete if Known		
Substitute fo	or form 4440	XBEMA!		Application Number	10/645,863	
INFORM	ATION I	- DISC	LOSURE	Filing Date	08/20/2003	
	-		LICANT	First Named Inventor	Jonathan C. HELLER	
(Use as many sheets as necessary)				Art Unit	2855	
				Examiner Name	Not yet assigned	
Sheet	1	of	3	Attorney Docket Number	29191 707 201	

		U.S. I	PATENT DOCU	MENTS	
Examiner Cite No. 1		Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2002/0048777	04/25/2002	Ali et al.	
		US-2002/0127237	09/12/2002	Salceda et al.	
		US-2002/0177140	11/28/2002	Salceda et al.	
		US-2003/0039983	02/27/2003	Sun et al.	
		US-2003/0064377	04/03/2003	Sun et al.	
		US-2003/0078739	04/24/2003	Norton et al.	
		US-2003/0111596	06/19/2003	Becker et al.	
		US-2003/0129760	07/10/2003	Aguilera et al.	
		US-2003/0175707	09/18/2003	Sun et al.	
		US-2003/0194739	10/16/2003	Ali et al.	
-		US-2003/0199001	10/23/2003	Pitt et al.	
		US-2004/0053333	03/18/2004	Hitt et al.	
*		US-6,593,298	07/15/2003	Jackowski et al.	
		US-6,599,877	07/29/2003	Jackowski et al.	
		US-6,602,855	08/05/2003	Jackowski et al.	
		US-6,617,308	09/09/2003	Jackowski et al.	
* **		US-6,620,786	09/16/2003	Jackowski et al.	
		US-6,620,787	09/16/2003	Jackowski et al.	·
		US-6,627,606	09/30/2003	Jackowski et al.	
		US-6,627,607	09/30/2003	Jackowski et al.	
		US-6,627,608	09/30/2003	Jackowski et al.	
		US-6,677,303	01/13/2004	Jackowski et al.	
		US-6,703,366	03/09/2004	Jackowski et al.	
	-	US-6,756,476	06/29/2004	Jackowski et al.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Date Considered

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Complete if Known		
Substitute fo	or form 1449	/PTO		Application Number	10/645,863	
INFORM	IATION I	DISC	LOSURE	Filing Date	08/20/2003	
STATEMENT BY APPLICANT (Use as many sheets as necessary)				First Named Inventor	Jonathan C. HELLER	
				Art Unit	2855	
				Examiner Name	Not yet assigned	
Sheet	2	of	3	Attorney Docket Number	29191.707.201	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>3</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Té		
		EP 0881494	12/02/1998	Boehringer Mannheim GmbH		Х		
		WO 00/23111	04/27/2000	Diadexus LLC				
		WO 03/058198	07/17/2003	Ciphergen Biosystems, Inc.		•		
		WO 03/086445	10/23/2003	Ciphergen Biosystems, Inc.				
		WO 03/089937	10/30/2003	Thermo Finnigan, LLC				
	-	WO 2004/012588	02/12/2004	The Johns Hopkins University; Ciphergen Biosystems, Inc.				
		WO 2004/013609	02/12/2004	The Johns Hopkins University; Ciphergen Biosystems, Inc.				
Examiner	T		***************************************	Date				

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				Complete if Known		
Substitute f	or form 14	49/PTO		Application Number	10/645,863	
			CLOSURE	Filing Date	08/20/2003	
			PLICANT	First Named Inventor	Jonathan C. HELLER	
(Use	as many shee	ets as nec	cessary)	Art Unit	2855	
				Examiner Name	Not yet assigned	
Sheet	3	of	3	Attorney Docket Number	29191.707.201	

		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbe						
		AURIOLA, Seppo et al., "Enhancement of sample loadings for the analysis of oligosaccharides isolated from <i>Pseudomonas aeruginosa</i> using transient isotachophoresis – electrospray – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2665-2676.						
		FIGEYS, Daniel et al., "High sensitivity analysis of proteins and peptides by capillary electrophoresistandem mass spectrometry: recent developments in technology and applications". <i>Electrophoresis</i> , (1998), 19:885-892.	•					
		GUO, Xu et al., "Analysis of metallonthioneins by means of capillary electrophoresis coupled to electrospray mass spectrometry with sheathless interfacing" Rapid Commun. Mass Spectrom. (1999), 13:500-507.						
		KAISER, Thorsten et al., "Capillary electrophoresis coupled to mass spectrometry to establish polypeptide patterns in dialysis fluids". <i>Journal of Chromatography A</i> (2003), 1013:157-171.						
		NEUSUB, Christian et al., "A robust approach for the analysis of peptides in the low femtomole range by capillary electrophoresis-tandem mass spectrometry". <i>Electrophoresis</i> (2002), 23:3149-3159.						
		RHODE, E. et al., "Comparison of protein mixtures in aqueous humor by membrane preconcentration – capillary electrophoresis – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2361-2370.						
		STROINK, Thom et al., "On-line coupling of size exclusion and capillary zone electrophoresis via a reversed-phase C18 trapping column for the analysis of structurally related enkephalines in cerebrospinal fluid". Electrophoresis (2003), 24:897-903.						
	•	WITTKE, Stefan et al., "Determination of peptides and proteins in human urine with capillary electrophoresis-mass spectrometry, a suitable tool for the establishment of new diagnostic markers". Journal of Chromatography A (2003), 1013:173-181.						
		·						

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